IN THE DRAWINGS

Please add new Figure 21.

Attachment: New Sheet including new Figure 21

COMMENTS

Claims 122-133 remain pending in the present application, Claims 124, 127, and 128 having been amended. The claims set forth above include markings to show the changes made by way of the present amendment, deletions being in ~~strikeout~~ and additions being underlined.

In response to the Office Action mailed October 4, 2005, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Niedospial, Jr. Does Not Anticipate Claims 127, 130, or 131

Claims 127, 130, and 131 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,287,289 issued to Niedospial, Jr. Applicant respectfully traverses the present rejection.

Niedospial, Jr. is directed to a multiple use universal connector. As shown in Figure 8 of Niedospial, Jr., the IV bag 10 has an outlet hose 14 and a connector 30. The connector 30 has a distal end 32 connected to the hose 14. The proximal end 52 of the connector 30 is connected to a cap 60. The proximal end 52 also includes a valve in the form of an "elastomeric diaphragm 90". Niedospial, Jr., col. 7, l. 60. Nothing in Niedospial, Jr. is directed to suction hose or suction hose kits.

Niedospial, Jr., fails to teach a medial suction hose kit that includes a suction hose and a connector with a first inner diameter, a second inner diameter, and a third inner diameter, wherein the first and second inner diameters are larger than the third inner diameter, and the first inner diameter is larger than the second inner diameter.

Applicant acknowledges that Examiner's explanation that the term "suction" does not provide a structural limitation to the claims, even in the context of Claim 130. Applicant respectfully disagrees.

The Niedospial, Jr. reference is directed to an IV related device; a device that allows fluid to flow in the human body by the pressure generated by gravity. Intravenous bags and their associated hoses (e.g., hose 14 of Niedospial, Jr.) are only subjected to positive pressures. There is no teaching or suggestion in the cited references that IV bags are ever subjected to suction. Thus, there is no suggestion that the hoses disclosed in Niedospial, Jr. should be designed for suction or aspiration.\ techniques used in surgeries.

Thus, the hoses (e.g., hose 14 of Niedospial, Jr.) is not *necessarily* capable of performing as medical suction hose. Rather, it is possible that the hose 14 of Niedospial, Jr. would collapse if subjected to the vacuum pressures used in wound aspiration procedures commonly used in surgeries.

Additionally, Niedospial, Jr. fails to teach or suggest a medical suction hose kit, as noted above, in which the connector does not have a valve. In some portions of surgical suction systems, valves can cause irregularities in the flow of fluid and debris flowing therethrough, and thus, valves are not appropriate for such portions of surgical suction systems.

In contrast, Claims 127 now recites a "medical suction hose kit comprising a sterilized package containing a sterilized length of first suction hose, the first suction hose having first and second hose ends, a first hose outer diameter and a first hose inner diameter, at least a first connector disposed at the first end, the first connector having a first connector end defining first connector inner diameter, a second connector end defining a second connector inner diameter, and a partition disposed between the first and second ends and defining a third connector inner diameter that is smaller than both of the first and second inner diameters, the first connector inner diameter being about the same as the first hose outer diameter such that the first end of the hose fits into the first connector end, the second connector inner diameter being smaller than the first connector inner diameter."

For example, with regard to the non-limiting embodiment shown in new Figure 21, the connector 126' includes an inner connector diameter 138 that is about the same as an inner diameter of the prior art suction hose 128, as well as the inner diameter of other surgical suction devices. *See* paragraph [0233] and Figure 15. However, the connector 126' also includes a second connector inner diameter 134' that is sized to receive the larger diameter suction hose 5'. Thus, the connector 5' can be used to connect the larger diameter hose 5' with smaller standard-sized equipment.

This kit provides an important advantage in surgical suction/aspiration procedures. For example, as noted at paragraph [0036]-[0039] of the present Application:

> **[0036]** During certain medical procedures, only liquids such as bodily fluids, humors, or irrigation fluid, is removed with a suction device. The typical 5-6mm tubing does not suffer from a clogging problem when only liquids are being suctioned. However, during certain types of surgery, such as orthopedic surgery, for example, a significant amount of bodily

tissues can be drawn into a suction device. It has been found that the conventional 5-6mm I.D. tubing commonly used in operating rooms suffers from a bottle-necking problem, due in part to the packaging technique used in marketing the tubing. More specifically, the conventional 5-6mm tubing commonly stocked for operating room use is folded into a sterilized package. The tubing is soft and flexible. Typically, the tubing is between 5 and 20 feet long. Thus, when the tubing is folded, the tubing collapses in the area of each fold. After the tubing has been stored for a significant amount of time, the collapsed portions of the tubing, usually in the area of the folds, remain in a partially collapsed state.

[0037] During an orthopedic operation, such as a joint replacement, many bone chips and clumps of tissue must be removed from the wound prior to closing. Thus, an orthopedic surgeon typically uses a small suction device having a suction tip with restricted openings, to suck out irrigation fluid, clumps of tissue, and bone chips. The restricted openings are sized so as to prevent large clumps of tissue and bone fragments from entering the suction hose. However, despite the size of the restricted opening, tissue clumps and bone fragments pass through the restricted opening which are large enough to form clogs at bottlenecks in the suction circuit. When a clog forms in the suction tubing, it is often difficult to dislodge the debris causing the clog. Thus, it is often necessary to stop the procedure, shut off the vacuum device, replace the tubing, then continue the procedure. This interruption can increase the labor hours required for certain procedures, and thus represents additional costs suffered by the medical facility in performing the medical procedure.

[0038] It has been found that the partially collapsed portions of conventional suction tubing contributes significantly to the clogging problem. Another aspect of at least one of the inventions disclosed herein includes the realization that where a larger diameter suction tubing is partially collapsed, the resulting cross sectional size of the collapsed portion can be large enough to reduce the likelihood of clogs from forming at the partially collapsed portion.

[0039] Thus, in accordance with yet another aspect of at least one of the inventions disclosed herein, a suction hose kit comprises a sterilized package enclosing tubing having an inner diameter of at least about 8mm. As such, the tubing can be made from the typically-used soft plastic material and folded into a compact shape, without causing constrictions that cause the clogging problem associated with the conventional smaller diameter suction tubing.

The kit of Claim 127 thus allows a user to assemble a suction system in which a larger diameter hose can be used with equipment designed for smaller diameter hose. This helps surgical aspiration procedures in a number of ways.

For example, as noted above in the present Application, when surgical suction hosing is stored in a coiled configuration, it tends to form constrictions due to a flattening of the

inner lumen of the hose. By providing a medical suction hose kit with a larger diameter hose, clogging due to the deformations caused by packaging can be avoided.

Applicant thus submits that the relative size differences recited in the Claim 127 provide tangible improvements in the area of medical suction procedures. Thus, Applicant submits that Claim 127 clearly and non-obviously defines over the Niedospial, Jr. reference. Additionally, Applicant submits that Claims 130 and 131 also define over the Niedospial, Jr. reference, not only because they depend from Claim 127, but also on their own merit.

Bryan et al. Does Not Anticipate Claims 127 or 130-133

Claims 127 and 130-133 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,582,165 issued to Bryan et al. Applicant respectfully traverses the present rejection.

Bryan et al. is directed to a multiple use universal connector. Nothing in Bryan et al. teaches or suggests a medical suction hose kit that includes a suction hose and a connector with a first inner diameter, a second inner diameter, and a third inner diameter, wherein the first and second inner diameters are larger than the third inner diameter, and the first inner diameter is larger than the second inner diameter.

In contrast, Claim 127 now recites a "medical suction hose kit comprising a sterilized package containing a sterilized length of first suction hose, the first suction hose having first and second hose ends, a first hose outer diameter and a first hose inner diameter, at least a first connector disposed at the first end, the first connector having a first connector end defining first connector inner diameter that is about the same as an inner diameter of a surgical suction device having an outer diameter that is smaller than the first hose outer diameter, the first connector having a second connector inner diameter that is sized to receive the outer surface of the suction hose, the first inner diameter being larger than the first connector inner diameter, without any valve being disposed in the connector."

As noted above with respect to the rejection of Claims 127, 130, and 131 as being anticipated by Niedospal, Applicant submits that this configuration provides significant advantages over the cited references. Thus, Applicant submits that Claim 127 clearly and non-obviously defines over the Bryan et al. reference. Additionally, Additionally, Applicant submits that Claims 130 and 131 also define over the Niedospial, Jr. reference, not only because they depend from Claim 127, but also on their own merit

Bryan et al. Does Not Make Claims 122-126 and 128 Obvious

Claims 122-126 and 128 stand rejected under 35 U.S.C. § 103(a) as being obvious over Bryan et al.. Applicant respectfully traverses the present rejection. However, in order to expedite prosecution of the present application, Applicant has amended Claim 128 into independent form. Applicant submits that the mere amendment of Claim 128 into independent for does not change or affect the scope of Claim 128, and thus, this amendment is not a narrowing amendment. Applicant therefore submits that all of the equivalents of recitations original Claim 128 are also equivalents of the present recitations of Claim 128. In any event, Applicant expressly reserves the right to further prosecute the original versions of Claims 122-126, and 128 through continuation practice.

As noted above, Bryan et al. is directed to a multiple use universal connector. However, as noted by the Examiner, Bryan et al. fails to teach a kit including a sterilized package containing a length of suction hose having an inner diameter of at least about 8 millimeters.

It was the Examiner's position that mere changes in the **"relative size"** of an element are not sufficient to patentably distinguish a claimed invention over the prior art. However, Applicant would like to focus on the supporting quote from the *Gardner* decision set forth in the Office Action.

In particular, the Office Action includes the explanation that "where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device **and a device having the claimed relative dimensions would not perform differently than the prior art device**, the claimed device was not patentably distinct from the prior art device." MPEP 2144.04 (Emphasis added).

Applicant, as noted above, has set forth ample evidence that the kit of Claim 122 *would in fact perform differently* than that shown in the cited references. For example, firstly, Bryan et al. is in fact silent as to the dimensions of the hoses disclosed therein. The present Application, however, indicates that operating room suction hoses usually have an inner diameter of 6 millimeters. *See* paragraph Nos. [0232]-[0233] of the present Specification. Again, as admitted by the Examiner, Bryan et al. fails to teach suction hosing having an inner diameter of 8 millimeters.

The present Specification includes a long and substantive discussion of the advantages of using 8 millimeter suction hosing with the standard 6 millimeter equipment.

For example, paragraphs [0036]-[0039] reproduced above provide such a substantive discussion. Thus, Applicant has established that the 8 millimeter hosing does perform differently than the standard 6 millimeter hosing commonly used in surgical procedures. Thus, Applicant submits that the combination of Bryan et al. and the legal precedent of MPEP § 2144.04 does not provide a prima facie case of obviousness.

In contrast, Claim 122 recites a "medical kit comprising a sterilized package containing a sterilized length of suction hose, the suction hose having an inner diameter of at least about 8 millimeters."

Claim 128 now recites a "medical suction hose kit comprising a sterilized package containing a sterilized length of suction hose, the suction hose having first and second hose ends and a first hose inner diameter, at least a first connector disposed at the first end, the first connector having a first connector end defining first connector inner diameter that is about the same as the first hose inner diameter, the first connector having a second connector inner diameter that is smaller than the first connector inner diameter, wherein the second connector inner diameter is about 6 millimeters and the first connector inner diameter is about 8 millimeters."

Applicant thus submits that Claims 122 and 128 clearly and non-obviously define over the Bryan et al. references, whether or not combined with the legal precedent of MPEP § 2144.04. Additionally, Applicant submits that Claims 123-126 also define over the cited art, not only because they depend from Claim 122, but also on their own merit.

Response to Drawing Objection

Applicant acknowledges the Examiner's objection to the drawings. Attached hereto on a separate page is new Figure 21 which illustrates the recitations of Claims 127-133. Applicant submits that no new matter has been introduced.

Amendments To The Specification Correct Minor Errors

The above amendments to the Specification correct a minor informality and also provide reference to new Figure 21. All of the changes to the present Specification are fully supported by the Application as originally filed and thus no new matter has been introduced. Applicant thus respectfully requests the present amendments be entered.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims and drawings. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 6, 2006

By: _____

Michael A. Guiliana
Registration No. 42,611
Attorney of Record
2040 Main Street
Fourteenth Floor
Irvine, CA 92614
(949) 760-0404

2260217_1
020606